REMARKS

Claims 1-3 and 5-12 were examined. No claims are added, amended or canceled. Claims 1-3 and 5-12 remain in the Application.

The Patent Office rejects claims 1-3 and 5-12 under 35 U.S.C. §103(a) as obvious over U.S. Patent No. 5,662,107 of Sakariassen (Sakariassen) in view of U.S. Patent No. 6,162,202 of Sicurelli, et al., (Sicurelli), U.S. Patent No. 5,800,395 of Botich et al. (Botich) or U.S. Patent No. 5,817,074 of Racz (Racz).

Sakariassen discloses a device for *in vitro* measurement of a tendency to form thrombi in people and animals under simulated *in vivo* conditions. See Abstract. Blood is pumped at a constant flow rate through at least one flow channel and the pressure difference between the pressures upstream and downstream of a thrombogenesis unit, due to a thrombus formed in the flow channel, is measured. See Abstract. Figure 1 shows a device including needle 1 that may inserted into a suitable vein. See col. 4, lines 47-49. Needle 1 is successively connected to different members beginning with tubes 2 and adaptor 3-1. T-tube 4 with pressure sensor 5-1 is next to measure a fluid pressure before thrombosis chamber 6. This is followed by second T-tube 4 with pressure sensor 5-2 for measuring the fluid pressure after thrombosis chamber 6 and is connected to the downstream side of thrombosis unit 6. Finally, the device includes adaptor 3-2 for a syringe 10.

The device for *in vitro* measurement of a tendency to form thrombi is intended for needle 1 to be placed in a vein. The remainder of the device is intended to reside outside the body, hence the description as *in vitro* device. In other words, each of elements 4, 5-1, 5-2, 11 and 8 reside outside the body. Further, blood is removed from the body via syringe 10 (see direction of arrow in Figure 1). It is not discussed in Sakariassen that a fluid (e.g., a drug) is intended to be introduced into the vein in which the device is connected.

Sicurelli discloses a flexible irrigation syringe tip for irrigating and delivering medication to intra-tooth canals during endodontic route canal treatment. *See* column 4, lines 15-18.

> As shown in FIG. 4 flexible syringe needle 10c of syringe 1c may have dispensing ports as lateral side ports dispensing fluid substantially transverse to a longitudinal axis of flexible syringe needle 10c, or a plurality of longitudinally extending, spaced apart

> lateral side ports 17c, wherein the plurality of lateral side ports 17c extend between the fluid discharge end 15c and connecting end 12c.

Col. 4, lines 51-57. Sicurelli notes that its device "may also be used to introduce fluids or medicine into body cavities such as a vascular blood vessel or vessels during vascular surgery, or into foramina holes in bones during surgery, or to negotiate within body cavities around rigid surfaces of bones or artificial steel plates during orthopedic surgery." Col. 3, lines 48-54.

Botich describes a medical device having an automatically retractable needle for presenting premature or inadvertent retraction of the needle. With reference to Figure 5, Botich describes needle 215 having hole 229 formed in the side and plug 230 is positioned in the rear end 218 of the needle. The needle 215 is propelled rearwardly during retraction of needle 215, gas or fluid in the chamber, into which the needle is moving is forced to flow with closed rear end of needle 215 as indicated by line 216. Hole 229 is positioned sufficiently toward the rear of the needle such that it is located adjacent a region 217 of reduced air pressure created by streamline 216 of fluid or gas around the closed rear end of the needle. See, col. 9, line 59 through col. 10, line 3. Hole 229 is not intended to be inserted into body tissue or a vessel in the body.

Racz discloses a needle having a side port positioned that a predetermined distance from the needle tip. If the needle is placed such that the needle tip opening is under an anterior longitudinal ligament which results in the needle tip opening being constricted, the side port allows directional injection. See Abstract.

Independent claim 1 describes a system including a needle comprising a body capable of penetrating tissue with an opening and at least one aperture located at a predetermined distance from the opening. The system also includes a fluid measurement assembly coupled with a portion of the needle to measure pressure of a fluid dispensed in the needle. The pressure measurement assembly is configured to measure (1) a first pressure that is the pressure of the fluid as the fluid is dispensed through the needle at a constant rate; (2) a second pressure that is a pressure change when the needle contacts the tissue and the first opening becomes occluded; and (3) a third pressure that is a second pressure change when the needle penetrates the tissue and the aperture becomes occluded.

To rely on a reference under 35 U.S.C. §103(a), it must be analogous prior art. The reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the inventor was concerned. MPEP 2141.01(a).

Claim 1 is directed to a system for detecting tissue contact by a needle and needle penetration depth into tissue. See Application, paragraph [0002]. Such a system finds beneficial use in delivering (e.g., injecting) fluid (e.g., drug) into a tissue penetrated by the needle.

Sakariassen is directed at *in vitro* measurement of a tendency of blood to form thrombi by simulating thrombosis outside the body. Its needle only needs to contact the vein such that blood may be withdrawn from the vein. The connection of the pending claims and Sakariassen extends only to puncturing tissue (e.g., a vein). Sakariassen in that regard is no different than what has been done for many years. Sakariassen has no relation to monitoring penetration unto tissue.

Sakariassen also does not describe penetrating a vein sufficiently to occlude a laterally placed aperture on its needle. Accordingly, assuming apertures are sensor 5-1 or sensor 5-2, such apertures are not configured to become occluded. Further, any pressure measurement assembly is not configured, for example, to measure a pressure that is a pressure change when the needle contacts tissue (e.g., the vein) and an opening (end) of the needle becomes occluded or a pressure that is a second pressure change when the needle penetrates the tissue and an aperture (sensor 5-1 or sensor 5-2) becomes occluded.

Botich describes a pressure release port in a needle, not a port in a needle intended to contact tissue and become occluded. Adding the teachings of Botich to Sakariassen does not teach adding an aperture where a fluid pressure measurement assembly would be configured to measure a pressure when a needle penetrates tissue and the port becomes occluded. There would similarly be no motivation to add such a feature to the device of Sakariassen.

Sicurelli and Racz disclose a side port on a needle that may be used for infusion. Since Sakariassen is withdrawing blood from a vein into an *in vitro* device having openings, there is nothing in Sakariessen to suggest the desirability or predictability of combining it with Sicurelli or Racz for a dispensing port.

For the above-state reasons, claim 1 is not obvious over the combined teachings of Sakariassen, Sicurelli, Botich and Racz. Claims 2-3 and 5-12 depend from claim 1 and therefore contain all the limitations of that claim. For at least the reasons stated with respect to claim 1, claims 2-3 and 5-12 are not obvious over the cited references.

Applicant respectfully requests that the Patent Office withdraw the rejection to claims 1-3 and 5-12 under 35 U.S.C. §103(a).

CONCLUSION

In view of the foregoing, it is believed that all claims now pending patentably define the subject invention over the prior art of record and are in condition for allowance and such action is earnestly solicited at the earliest possible date.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17, particularly extension of time fees.

Respectfully submitted,
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I hereby certify that this correspondence is being submitted electronically via EFS Web on the date shown below to the United States Patent and Trademark Office.

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